MICHBIO

DRIVING BIOSCIENCES INDUSTRY GROWTH

October 28, 2009

Honorable Members
Michigan Senate Health Policy Committee

Re: Testimony Regarding SBs #647-652 and Regulatory Oversight of Stem Cell Research

Mr. Chairman, Honorable members of the Committee. Good afternoon. My name is Stephen Rapundalo and I am the President and CEO of MichBio, the statewide biosciences industry association.

On behalf of more than 230 bioscience companies, academic and clinical research institutions and associated bioscience service providers and organizations, I would like to state our opposition to Senate bills #647-652 under your consideration currently.

The fact is that sufficient regulatory oversight exists at the federal level. The proposed bills do nothing more than needlessly add a bureaucratic burden and associated costs for no apparent enhancement in compliance value. Moreover, it sets back the early gains Michigan has made as a growing locus for stem cell research and commercialization. The citizens of Michigan spoke clearly last November. Let's move forward together with concrete efforts to enhance the business and regulatory environment supporting stem cell research and the biosciences industry as a whole, instead of resorting to thinly-veiled, self-serving political tactics to undermine that ballot verdict.

A number of organizations and federal agencies have provided considerable and comprehensive commentary and issued specific regulatory guidelines for conducting stem cell research. In all cases, these specify rigorous ethical standards for scientists working with human embryonic stem cells, and seek to promote responsible, transparent and uniform practices. Anyone associated with academic research and a clinical setting knows of the strict regulations in place that govern all human subject research.

Permit me do a brief recap. Two Health and Humans Services agencies, the National Institutes of Health (NIH) and Federal Drug Administration (FDA), regulate stem cell research. NIH, the medical and behavioral research agency within HHS, regulates stem cell research that it funds in compliance with Administration policy. On July 7, 2009, the

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NIH issued final guidelines after considerable public input on the governing the use of human embryonic stem cells. Clinical research that involves recombinant DNA or gene-transfer research is further reviewed by the NIH's Recombinant DNA Advisory Committee. Although only applicable to federally funded research, all public and private institutions require compliance with NIH guidelines. The FDA, the agency that ensures the safety and efficacy of food, drugs, medical devices and cosmetics, regulates stem cell research aimed at the development of any "product" subject to its approval.

Two non-federal entities have also played a role in regulating stem cell research. The National Academy of Sciences developed voluntary guidelines for deriving, handling and using human embryonic stem cells in 2005, with added amendments in 2007 and 2008. Again, the NAS guidelines are followed by most research institutions and codified by some states. The NAS guidelines cover ethical procurement of gametes, derivation of cell lines, international collaboration, informed consent, and a system of guidance at the local level through Embryonic Stem Cell Research Oversight committees. The International Society for Stem Cell Research (ISSCR), "an independent, nonprofit organization to foster the exchange of information on stem cell research," developed guidelines in 2006 that are congruent with the NAS guidelines. And in 2008 the ISSCR issued guidelines for the translation of human embryonic stem cell research into applied clinical therapies. They have even issued a Patient Handbook on Stem Cell Therapies.

Aside from local oversight through ESCRO committees, several additional layers of local oversight exist. These include Institutional Review Boards, Animal Care and Use Committees, and Institutional Biosafety Committees. Depending on the circumstances other institutional committees such as hospital clinical ethics committees might be involved. Oversight is typically provided by multiple groups noted, and not in isolation of the others.

Regulatory and ethical aspects aside, does the State truly have the means to implement more regulatory oversight? Given your severe budgetary constraints and already announced department cutbacks on basic services in healthcare, we seriously doubt that the State has the fiscal capacity to develop and manage the new paper trail that will be required as a consequence of the proposed legislation?

More importantly, the bills will have untoward consequences on Michigan's image as a business environment open and friendly to bioscience and medical innovation and commercialization. Economic studies show, beyond a doubt, that technological change is the major driving force for sustained economic growth. As it stands, Michigan has lost its competitive stature in the domestic and global biosciences industry. Once a second tier state, perhaps even a towards-the-bottom top tier state, Michigan is now viewed as being in the third to bottom tier. The bi-annual BIO-Batelle State Biosciences Initiatives Report has shown repeatedly that having a favorable business and regulatory environment is a critical success factor in growing a vibrant and economically beneficial

biosciences industry. MichBio and its many partners around the state have been working very hard to enhance the visibility of our biosciences industry and the richness we have in assets, infrastructure, resources, and talent.

How quickly can an economic impact be realized following a change in embryonic stem cell policy? Just since last November we've seen an uptick in academic research efforts and funding, the launch of the Stem Cell Research Commercialization Center at Techtown and the announcement that Michigan will host the 2010 World Stem Cell Congress. I'm confident that without further impediments we can continue to garner more attention and investment in our stem cell research efforts and biosciences industry as a whole. Let's insure that academic scientists, entrepreneurs, biotech companies and investors don't pass us by on their way to states that support cutting-edge scientific discovery.

Michigan needs bold leadership to move its economy forward. The biosciences industry is already a significant high-tech growth sector employing almost 100,000 people directly and indirectly and contributing $9.6 billion to the state's GRP. We should be doing everything possible legislatively and programmatically to expand our economic development efforts in the biotechnology sector and reassert the state as a leader in the industry. Bills such as those under consideration only serve to take us backwards rather than forward by tarnishing our image and reputation. Now is not the time to be short-changing our future economic sustainability, especially recognizing that sufficient regulatory oversight already exists at the federal level.

Thank you.

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